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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,663	09/26/2005	Zhongyong Wei	101022-1P US	3011

22466 7590 02/13/2007
ASTRA ZENECA PHARMACEUTICALS LP
GLOBAL INTELLECTUAL PROPERTY
1800 CONCORD PIKE
WILMINGTON, DE 19850-5437

EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/550,663

Applicant(s)

WEI ET AL.

Examiner

Niloofar Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/26/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-7, and 12-17 are pending and claims 8-11 are cancelled.

2. ***Priority***

This application is filed on 09/26/2005, which is a 371 of PCT/SE04/00472, filed on 03/26/2004, which claims the priority of SWEDEN 0300908-1, filed on 03/31/2003.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, and 12-17 are rejected because the term "R¹ and R³" is confusing. Does it mean "R¹" being alkyl group consisting of C₁₋₁₂ or any groups contain of C₁₋₁₂? Correction is required.

4. Claims 1-7, and 12-17 are rejected because the term "Ar" is confusing. Does it mean "Ar" being C₄₋₁₂ aromatic ring? Correction is required.

5. Claims 1-7, and 12-17 are rejected because the term "X" is confusing. Does it mean "X" being C₁₋₁₀ alkyl group? Correction is required.

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6. Claim 12 is rejected because the claims are self-conflicting.

Pharmaceutical composition by definition must be effective yet non-toxic.

Claim 12 is pharmaceutical composition without dosage limitation i.e.

included both ineffective and toxic amount. It is recommended that

"therapeutically effective amount" be incorporated in the claim.

7. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation

needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

- 1) The breadth of the claims.
- 2) The nature of the invention,
- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,
- 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to a method for the therapy of pain in a warm-blooded animal using a compound of formula I.

The state of the prior art: " In-life clinical observations, values for WBC parameters, and changes of lymphoid organ weights suggested immune effects. Elevated IgM titers indicated increased antibody formation in HCB-exposed rats. Reduced numbers of antibody-forming cells in PFC assay indicated impaired T-cell-dependent humoral immunity by CSA, which was not seen for HCB. Altered fractions for B- and T-cell subpopulations were identified in spleen for both substances. Results of the present model studies, with CSA and HCB indicated that enhanced examinations led to data important to identify effects on the immune system." (Schulte et al., Regulatory Toxicology and Pharmacology, 2002, Vol. 36, pages 12-21).

“ PCBs possess a variety of biological effects, including alterations in growth development and metabolism, that may be dependent on insulin. However, no reports on the action of PCBs on cells which produce and secrete insulin are available. The current study examined the ability of a commercial mixture of PCBs and three specific PCB congeners, to alter the release of insulin using the hormone producing cell line RINm5F.” (Fischer et al., Life Sciences, 1996, Vol. 59, pages 2041-2049).

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claim 1 would be useful for treating a pharmacological condition in a subject.

Amount of guidance/working examples: On page 26 of the specification, applicant has examples of test compounds for activity of hCB₁ and hCB₂ assay. However, applicant has not guidance or examples for treating pain in a warm-blooded animal.

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The breadth of the claims: The breadth of claims is drawn to a method for the therapy of pain in a warm-blooded animal using a compound of formula I.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating pain in a warm-blooded animal, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claim 13, for treating pain in a warm-blooded animal, have been enabled by the instant specification.

8. *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

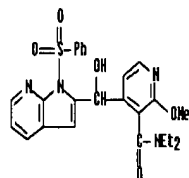
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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Desarbres et al., Tetrahedron, Vol. 53, pages 3637-3648. Desarbres et al. disclosed the instant claimed compounds, which is from the STN search are

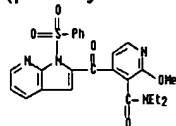
RN 189089-95-0

CN 3-Pyridinecarboxamide, N,N-diethyl-4-[hydroxy[1-(phenylsulfonyl)-1H-pyrrolo[2,3-b]pyridin-2-yl]methyl]-2-methoxy



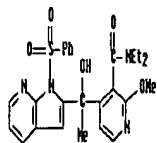
RN 189089-96-1

CN 3-Pyridinecarboxamide, N,N-diethyl-2-methoxy-4-[[1-(phenylsulfonyl)-1H-pyrrolo[2,3-b]pyridin-2-yl]carbonyl]



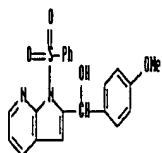
RN 189089-97-2

CN 3-Pyridinecarboxamide, N,N-diethyl-4-[1-hydroxy-1-[1-(phenylsulfonyl)-1H-pyrrolo[2,3-b]pyridin-2-yl]ethyl]-2-methoxy



RN 189089-84-7

CN 1H-Pyrrolo[2,3-b]pyridine-2-methanol, a-(4-methoxyphenyl)-1-(phenylsulfonyl)



instant claim is anticipated by Desarbres et al.

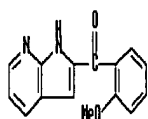
. Therefore, the

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9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mahboobi et al., Journal of Medicinal Chemistry, 2001, Vol. 44, pages 4535-4553. Mahboobi et al. disclosed the instant claimed compounds, which is from the STN search are

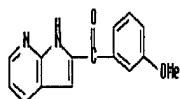
RN 370581-48-9

CN Methanone, (2-methoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl



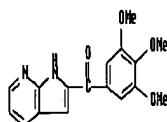
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CN Methanone, (3-methoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl



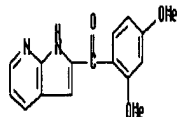
RN 370581-50-3

CN Methanone, 1H-pyrrolo[2,3-b]pyridin-2-yl(3,4,5-trimethoxyphenyl)



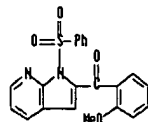
RN 370581-51-4

CN Methanone, (2,4-dimethoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl



RN 370580-89-5

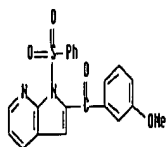
CN 1H-Pyrrolo[2,3-b]pyridine, 2-(2-methoxybenzoyl)-1-(phenylsulfonyl)



RN 370580-90-8

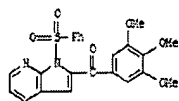
CN 1H-Pyrrolo[2,3-b]pyridine, 2-(3-methoxybenzoyl)-1-(phenylsulfonyl)

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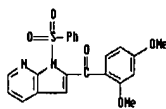
RN 370580-91-9

CN 1H-Pyrrolo[2,3-b]pyridine, 1-(phenylsulfonyl)-2-(3,4,5-trimethoxybenzoyl)



RN 370580-92-0

CN 1H-Pyrrolo[2,3-b]pyridine, 2-(2,4-dimethoxybenzoyl)-1-(phenylsulfonyl)

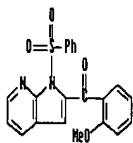


Therefore, the instant claim is anticipated by Mahboobi et al.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Beckers et al. WO01/82909. Beckers et al. disclosed the instant claimed compounds, which is from the STN search are

RN 370580-89-5

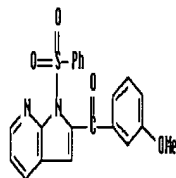
CN 1H-Pyrrolo[2,3-b]pyridine, 2-(2-methoxybenzoyl)-1-(phenylsulfonyl)



RN 370580-90-8

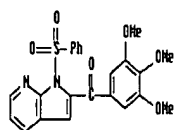
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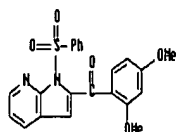
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CN 1H-Pyrrolo[2,3-b]pyridine, 1-(phenylsulfonyl)-2-(3,4,5-trimethoxybenzoyl)



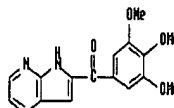
RN 370580-92-0

CN 1H-Pyrrolo[2,3-b]pyridine, 2-(2,4-dimethoxybenzoyl)-1-(phenylsulfonyl)



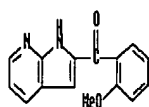
RN 370581-50-3

CN Methanone, 1H-pyrrolo[2,3-b]pyridin-2-yl(3,4,5-trimethoxyphenyl)



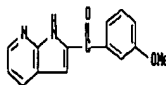
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CN Methanone, (2-methoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl



RN 370581-49-0

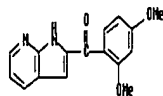
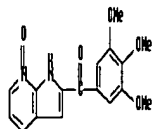
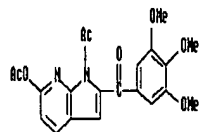
CN Methanone, (3-methoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl-



RN 370581-51-4

CN Methanone, (2,4-dimethoxyphenyl)-1H-pyrrolo[2,3-b]pyridin-2-yl-

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**RN** 370581-56-9**CN** Methanone, (7-oxido-1H-pyrrolo[2,3-b]pyridin-2-yl)(3,4,5-trimethoxyphenyl)**RN** 370581-58-1**CN** 1H-Pyrrolo[2,3-b]pyridin-6-ol, 1-acetyl-2-(3,4,5-trimethoxybenzoyl)-, acetate

. Therefore,
the instant claim is anticipated by Beckers et al.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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NILOOFAR RAHMANI

02/06/2007

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MARGARET D. SEAMAN

PRIMARY EXAMINER

GROUP 1625